REMARKS

Claims 1-8 are pending. The amendments to claims 1 and 5 find support at page 2, lines 33 to 43, and page 16, lines 22 to 24. New claim 7 further finds support in Example 2 wherein PEG is used in an amount of 50%.

Claims 1-6 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Baert et al. (US 6,365,188) in view of Stella et al. (US 6,046,177) in further view of Murata et al. (US 5,500,221). Applicants respectfully traverse this rejection.

Murata (US 5,500,221) describes a sustained-release suppository preparation which comprises an acidic drug or a salt thereof and an acidic compound or a pH buffering agent. Murata further describes that the suppository preparation may, among other things, additionally contain polymers, such as hydroxypropylmethylcellulose (HPMC) and polyvinylpyrrolidone (PVP). These polymers are incorporated in order to adjust the release rate of the drug (see col. 3, lines 18 - 20). Since the object of the Murata invention is to retard the release of the suppository drugs (see col. 1, lines 35 - 48), the use of the polymers "in order to adjust the release rate of the drug" (col. 3, line 20) means that the polymers are intended to retard the release of the drug and definitely not to accelerate the release rate. The Murata reference does not contain any examples showing the influence of the polymeric components on the release rate of the suppository drugs.

Since in the Murata reference, no distinction is made between the influence of hydroxypropylmethylcellulose on the one side and polyvinylpyrrolidone on the other side on the release rate of drugs, a person skilled in the art would have deduced that replacing hydroxypropylmethylcellulose by PVP in the Stella reference (US 6,046,177), e.g. in the composition of example 10, results in a drug composition which also shows a slow release rate of the drug (i.e. like the composition of example 10, where HPMC and minor amounts of PEG are used).

Accordingly, a person skilled in the art seeking to provide a method for producing dosage forms with a fast release rate of the drug would not have had the slightest motivation to use polymeric binders such as PVP or PEG in the drug composition because both from the Murata reference and from the Stella reference (here especially from example 10) he would have expected that this type of polymeric binders leads to dosage forms with a retarded drug release – especially when the binders are used in considerable amounts (such as 50-98% per weight, see

claim 8). In other words, the cited art teaches away from the present invention. A *prima facie* case of obviousness may be rebutted by showing that the art, in any material respect, teaches away from the claimed invention (MPEP 2144.05, paragraph III).

Additionally, the Examiner has suggested a showing of unexpected results, i.e. the criticality of the instant binders, to overcome the obviousness rejection. Applicants urge that the Examples of present specification demonstrate just that. Specifically, the Examples show that dosage forms prepared from a mixture containing the instantly claimed polymeric binders have a surprisingly fast drug release rate, although from the cited prior art references, as discussed above, a person skilled in the art would have expected the contrary.